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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and supply of infant formula, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. DELAURO introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety and supply of infant formula, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Keep Infant Formula Safe and On the Shelves Act of 2022''.

SEC. 2. PRODUCT SAFETY.

(a) INSPECTIONS AND AUDITS.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is amended by adding at the end the following:

''(j) INSPECTIONS AND AUDITS.—

''(1) IN GENERAL.—Not less than every 6 months, the Secretary shall inspect the facilities of each manufacturer of infant formula registered under subsection (c).

''(2) UNANNOUNCED INSPECTIONS.—Not later than 6 months after the date of enactment of the Keep Infant Formula Safe and On the Shelves Act of 2022, and not less than once per calendar year thereafter, the Secretary shall conduct unannounced inspections of the facilities of each manufacturer of infant formula registered under subsection (c), including such facilities with no history of notable regulatory findings.

''(3) AUTOMATIC COMPREHENSIVE FOOD SAFETY AUDIT.—If the Secretary makes a notable regulatory finding at any facility of a manufacturer of infant formula during an inspection or audit, the Secretary shall require such facility to undergo a comprehensive food safety audit that includes—

''(A) a root cause analysis;

''(B) enhanced testing; and

''(C) comprehensive environmental samples throughout the facility.

''(4) AUDITS.—The Secretary shall increase the frequency of comprehensive food safety audits of a facility of a manufacturer of infant formula registered under subsection (c) if there are persistent notable regulatory findings at such facility.

''(5) MICROBIAL TEST RESULTS.—

''(A) IN GENERAL.—During any inspection or audit by the Secretary of a facility of a manufacturer of infant formula, the manufacturer shall provide to the Secretary the results of all microbial tests conducted by or for the facility during the period of 15 years preceding the date of the inspection or audit.

''(B) FINES.—If the Secretary finds that a facility is in violation of subparagraph (A), such violation shall be treated as an infraction for purposes of imposing a fine in accordance with title 18, United States Code.''.

(b) CRONOBACTER SAKAZAKII.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the Council of State and Territorial Epidemiologists, shall consider adding cronobacter

sakazakii to the list of nationally notifiable diseases and conditions under the National Notifiable Diseases Surveillance System.

SEC. 3. SUPPLY.

(a) STRATEGIC NATIONAL STOCKPILE.—Not later than 90 days after the date of enactment of this Act, the Secretary of Agriculture, in consultation with the Assistant Secretary for Preparedness and Response of the Department of Health and Human Services and the Administrator of the Federal Emergency Management Agency, shall—

(1) perform an assessment of—

(A) short- and long-term storage of infant formula, including the possibility of storage of infant formula in a Federal stockpile; and

(B) models for distribution of infant formula during shortages; and

(2) submit a report to the Congress on the results of such assessment.

(b) NOTIFICATION BY MANUFACTURERS OF CIRCUMSTANCES THAT COULD LEAD TO A SHORTAGE OF INFANT FORMULA OR ESSENTIAL MEDICAL FOOD.—

(1) REQUIREMENT.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding the following at the end:

"SEC. 424. NOTICE OF CIRCUMSTANCES THAT COULD LEAD TO A SHORTAGE.

"(a) NOTICE REQUIREMENT.—Not later than 5 business days after a manufacturer of infant formula or essential medical food becomes aware of circumstances that could lead to a shortage of infant formula or essential medical food in the United States, such manufacturer shall give written notice of such circumstances to the Secretary.

"(b) DEFINITION.—In this section, the term 'essential medical food' means a food that—

"(1) is formulated to be consumed or administered enterally under the supervision of a physician;

"(2) is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation; and

"(3) is identified by the Secretary as being essential for any urgent medical condition.

"(c) FINES.—If the Secretary finds that a manufacturer of infant formula or essential medical food is in violation of the requirement of this section to give written notice, such violation shall be treated as an infraction for purposes of imposing a fine in accordance with title 18, United States Code.".

(c) LIST OF FACILITIES THAT COULD BE CONVERTED TO MANUFACTURE INFANT FORMULA.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by section 2(a), is further amended by adding at the end the following:

''(k) LIST OF FACILITIES THAT COULD BE CONVERTED.—The Secretary shall—

''(1) not later than 90 days after the date of enactment of this subsection, identify and compile a list of all manufacturing facilities in the United States that could be converted to manufacture infant formula in the event of a shortage;

''(2) on an annual basis, update such list; and

''(3) post such up-to-date list on the public website of the Food and Drug Administration.''.

(d) REPORTING BY MANUFACTURERS DURING A SHORTAGE.—Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), as amended by subsection (c), is further amended by adding at the end the following:

''(l) REPORTING BY MANUFACTURERS DURING A SHORTAGE.—In the event of a shortage of infant formula in the United States, the Secretary may require manufacturers of infant formula to report to the Secretary—

''(1) the quantity of infant formula in the inventories of such manufacturers and their distributors;

''(2) the location of recent or upcoming shipments of infant formula by such manufacturers and their distributors;

''(3) the capacity of such manufacturers and their distributors to redistribute their inventories of infant formula based on geographical needs; and

''(4) the quantity by which such manufacturers could increase their output of infant formula.''.

SEC. 4. USE OF AUTHORITIES UNDER THE DEFENSE PRODUCTION ACT OF 1950 FOR FOOD.

Section 101 of the Defense Production Act of 1950 (50 U.S.C. 4511) is amended by adding at the end the following:

''(e) TREATMENT OF FOOD.—For purposes of this title, title III, and title VII, food (including infant formula and the ingredients necessary to produce infant formula) is a critical material essential to the national defense.''.

SEC. 5. ENSURING WORKER SAFETY AND HEALTH.

The Assistant Secretary of Labor for Occupational Safety and Health shall issue a fact sheet and provide technical assistance to each manufacturer of infant formula registered under section 412(c) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 350a(c)) to promote compliance with occupational safety and health standards promulgated under section 6 of the Occupational Safety and Health Act of 1970. Such fact sheet and technical assistance shall include information on recognized hazards and on the specific occupational safety and health standards, and any other legal requirements under the Occupational Safety and Health Act of 1970, that apply to such manufacturer.